



PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE



5th Annual PHEMCE Stakeholders Workshop & BARDA Industry Day

Walter E. Washington Convention Center
Washington, DC
Monday, January 10, 2011

9:00 – 9:30
South Bldg
Third Floor
Ballroom C



Keynote Address



Opening Remarks

RADM Nicole Lurie, MD, MSPH (USPHS)

Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services



Secretary Kathleen Sebelius INVITED

U.S. Department of Health and Human Services

9:30 – 10:15
South Bldg
Third Floor
Ballroom C



Implementing the Recommendations of the Secretary's Medical Countermeasure Review



Andrew C. Weber

Assistant to the Secretary of Defense for Nuclear, Chemical and
Biological Defense Programs
U.S. Department of Defense



Margaret Hamburg, MD

Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services

10:15 – 10:30
South Bldg
Third Floor
Ballroom C



Overview of the National Health Security Strategy and Biennial Implementation Plan

Lisa G. Kaplowitz, MD, MHSA
Deputy Assistant Secretary for Preparedness and Response
Director, Office of Policy and Planning
U.S. Department of Health and Human Services

10:30 – 10:45
South Bldg
Third Floor
Pre-Function Area

Break

10:45 – 12:15
South Bldg
Third Floor
Ballroom C



PANEL: Optimizing Scarce Resources

Kevin Yeskey, MD
Deputy Assistant Secretary for Preparedness
and Response
Director, Office of Preparedness and
Emergency Operations
U.S. Department of Health and Human Services

Surge Capacity: Making It Real

Arthur L. Kellermann, MD, MPH
Director, RAND Health
Paul O'Neill-Alcoa Chair in Policy Analysis
RAND Corporation

PANEL: Effective Responsiveness at Local Levels

David Starr, MIA
Director, Countermeasures Response
Office of Emergency Preparedness and
Response
NYC Department of Health and Mental Hygiene
New York, New York

Robert P. Mauskopf, MPA
Colonel, USMC (ret)
Director, Emergency Preparedness
Virginia Department of Health

10:45 – 12:15
South Bldg
Third Floor
Ballroom B



PANEL: Expanding the Product Pipeline and Exploring Multiuse Potential

Robin A. Robinson, PhD
Deputy Assistant Secretary for Preparedness
and Response
Director, Biomedical Advanced Research and
Development Authority
U.S. Department of Health and Human Services

J. Kevin Judice, PhD
Chief Executive Officer
Chief Scientific Officer
Achaogen, Inc.

PANEL: Novel Methods to Foster Innovation

Jonathan Seals, PhD
Acting Director
Strategic Science and Technology Division
Biomedical Advanced Research and Development
Authority
Office of the Assistant Secretary for Preparedness
and Response
U.S. Department of Health and Human Services

Richard J. Hatchett, MD
Director for Medical Preparedness Policy
National Security Staff
The White House

12:15 – 1:30

Lunch On Your Own

Convention Center Concessions located in Middle Building, Second Floor



*This icon indicates sessions that will be webcast live on January 10 and 11
and archived thereafter on www.MedicalCountermeasures.gov.*

1:30 – 3:20

Breakout Discussion Sessions

South Bldg
Second Floor
Room 204 ABC

Pre-Event Positioning of Medical Countermeasures

Host: Elin Gursky, ScD, MSc

ANSER Analytic Services Contractor in support of
Division of Medical Countermeasure Strategy and Requirements
Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

South Bldg
Second Floor
Room 209 ABC

Community Preparedness for All-Hazards Response: Planning for At-Risk Populations

Host: Daniel Dodgen, PhD

Director
Division for At Risk Individuals, Behavioral Health, and Community Resilience
Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

South Bldg
Second Floor
Room 207 B

Building and Sustaining Medical Countermeasure Industries for CBRN Threats and Pandemic Influenza

Host: Gary L. Disbrow, PhD

Deputy Director, Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Host: Robert Huebner, PhD

Deputy Director, Influenza Division
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

South Bldg
Second Floor
Room 207 A

HHS Emerging Infectious Diseases Program

Host: Jonathan Seals, PhD

Acting Director, Strategic Science and Technology Division
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Host: Jennifer Gordon, PhD

AAAS Science and Technology Policy Fellow
Division of Medical Countermeasure Strategy and Requirements
Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Host: Dennis Dixon, PhD

Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases, National Institutes of Health
U.S. Department of Health and Human Services

South Bldg
Second Floor
Room 202 B

Contracting with the U.S. Government

Host: D. Andre Early, MPM

CBRN Contracts Section Chief and Contracting Officer
Office of Acquisitions Management, Contracts, and Grants
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Host: Ronald G. Manning, PhD

Chief, Chemical, Radiological & Nuclear Medical Countermeasures
Division of CBRN Medical Countermeasures
Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

3:20 – 3:50

South Bldg

Third Floor

Pre-Function Area

Break

3:50 – 5:15

South Bldg

Third Floor

Ballroom C



PANEL: Building Community Resilience

Lisa G. Kaplowitz, MD, MHSA

Deputy Assistant Secretary for Preparedness
and Response
Director, Office of Policy and Planning
U.S. Department of Health and Human Services

Lillian McDonald

Executive Director
Emergency, Community and Health Outreach
(ECHO)
Minnesota

PANEL: International Partnerships to Enhance Global Health Security

Maria Julia Marinissen, PhD

Director
Division of International Health Security
Office of Policy and Planning
Office of the Assistant Secretary for Preparedness
and Response
U.S. Department of Health and Human Services

Patrick Rajoelina

Secrétaire Général
Etablissement de Préparation et de Réponse aux
Urgences Sanitaires (EPRUS)
France

Lionel de Moissy, PharmD

Adjoint Pharmacien Responsable
Etablissement de Préparation et de Réponse aux
Urgences Sanitaires (EPRUS)
France

3:50 – 5:15

South Bldg

Third Floor

Ballroom B



PANEL: Enhancing the Medical Countermeasure Enterprise

George W. Korch, PhD

Principal Deputy Assistant Secretary for
Preparedness and Response
U.S. Department of Health and Human Services

Luciana Borio, MD

Senior Advisor for Medicine and Public Health
Acting Director, Office of Counterterrorism and
Emerging Threats
Office of the Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services

Carol Linden, PhD

Principal Deputy Director
Biomedical Advanced Research and
Development Authority
Office of the Assistant Secretary for
Preparedness and Response
U.S. Department of Health and Human Services

5:15 – 6:30

South Bldg

Third Floor

Ballroom A

Reception and Poster Session – Exhibit Hall



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**PUBLIC HEALTH EMERGENCY MEDICAL
COUNTERMEASURES ENTERPRISE**



5th Annual PHEMCE Stakeholders Workshop & BARDA Industry Day

Tuesday, January 11, 2011

**Walter E. Washington Convention Center
Washington, DC**

**Tuesday
January 11**

9:00 – 10:15

South Bldg
Third Floor
Ballroom C



Implementing the Recommendations of the Secretary's Medical Countermeasure Review



RADM Nicole Lurie, MD, MSPH (USPHS)

Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services



Michael Kurilla, MD, PhD

Director, Office of Biodefense Research Affairs
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases, National Institutes of Health
U.S. Department of Health and Human Services



RADM Ali S. Khan, MD, MPH (USPHS)

Assistant Surgeon General
Director, Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

10:15 – 10:45

North Bldg
First Floor

Break

10:45 – 12:15

Breakout Discussion Sessions

South Bldg
Second Floor
Room 204 ABC

Pre-Event Positioning of Medical Countermeasures

Host: Elin Gursky, ScD, MSc

ANSER Analytic Services Contractor in support of
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U.S. Department of Health and Human Services

South Bldg
Second Floor
Room 209 ABC

Community Preparedness for All-Hazards Response: Planning for At-Risk Populations

Host: Daniel Dodgen, PhD

Director
Division for At Risk Individuals, Behavioral Health, and Community Resilience
Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

South Bldg Second Floor Room 207 B	Novel Approaches to Medical Countermeasure Development	Host: Joseph Larsen, PhD Senior Project Officer, Broad Spectrum Antimicrobials Program Division of CBRN Medical Countermeasures Biomedical Advanced Research and Development Authority Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services
South Bldg Second Floor Room 207 A	HHS Emerging Infectious Diseases Program	Host: Jonathan Seals, PhD Acting Director, Strategic Science and Technology Division Biomedical Advanced Research and Development Authority Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services Host: Jennifer Gordon, PhD AAAS Science and Technology Policy Fellow Division of Medical Countermeasure Strategy and Requirements Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services Host: Dennis Dixon, PhD Chief, Bacteriology and Mycology Branch Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases, National Institutes of Health U.S. Department of Health and Human Services
South Bldg Second Floor Room 202 B	Small Business Strategies and Contracting with the U.S. Government	Host: D. Andre Early, MPM CBRN Contracts Section Chief and Contracting Officer Office of Acquisitions Management, Contracts, and Grants Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services Host: Ronald G. Manning, PhD Chief, Chemical, Radiological & Nuclear Medical Countermeasures Division of CBRN Medical Countermeasures Biomedical Advanced Research and Development Authority Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services Host: Nydia Sagna Small Business Specialist Office of Small and Disadvantaged Business Utilization U.S. Department of Health and Human Services

12:15 – 1:30	Lunch On Your Own <i>Convention Center Concessions located in Middle Building, Second Floor</i>
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1:30 – 3:30 South Bldg Third Floor Ballroom C	<div data-bbox="345 121 800 184"> PANEL: Detection and Surveillance </div> <div data-bbox="345 205 800 399"> <i>Situational Awareness: Strengthening Epidemiology and the Laboratory</i> CAPT Daniel Sosin, MD, MPH, FACP (USPHS) Deputy Director and Chief Medical Officer Office of Public Health Preparedness and Response Centers for Disease Control and Prevention U.S. Department of Health and Human Services </div> <div data-bbox="345 420 800 556"> Michael Walter, PhD Detection Branch Chief BioWatch Program Manager Office of Health Affairs U.S. Department of Homeland Security </div> <div data-bbox="345 604 800 667"> Public/Private Collaborations: What Works and What Doesn't </div> <div data-bbox="345 688 800 804"> Edward J. Gabriel, MPA, EMT-P, CEM, CBCP Director Global Crisis Management and Business Continuity The Walt Disney Company </div>	1:30 – 3:30 South Bldg Third Floor Ballroom B	<div data-bbox="982 121 1437 184"> PANEL: Access to Medical Countermeasures </div> <div data-bbox="982 205 1437 342"> Sally J. Phillips, PhD, RN Deputy Director Health Threats Resilience Division Office of Health Affairs U.S. Department of Homeland Security </div> <div data-bbox="982 363 1437 499"> Pamela Nutt, RN, BSN Chief Nurse / SNS Coordinator Office of Emergency Preparedness and Response Mississippi State Department of Health </div> <div data-bbox="982 520 1437 657"> Nicki Pesik, MD Senior Advisor for Medical Countermeasures Office of Public Health Preparedness and Response Centers for Disease Control and Prevention U.S. Department of Health and Human Services </div> <div data-bbox="982 678 1437 772"> <i>Evaluation of Potassium Iodide Pill Distribution and Nuclear Emergency Preparedness Programs</i> </div> <div data-bbox="982 772 1437 909"> James D. Blando, PhD Assistant Professor School of Community and Environmental Health College of Health Sciences Old Dominion University </div> <div data-bbox="982 930 1437 1140"> R. Thomas Warf Director Manufacturing, Facilities and Engineering Biomedical Advanced Research and Development Authority Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services </div>
3:30 – 3:50 South Bldg Third Floor Pre-Function Area	Break		
3:50 – 4:45 South Bldg Third Floor Ballroom C	Reports from Breakout Discussion Sessions		
	Moderator: George W. Korch, PhD Principal Deputy Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services		
4:45 – 5:00 South Bldg Third Floor Ballroom C	Workshop Summary and Closing		
	RADM Nicole Lurie, MD, MSPH (USPHS) Assistant Secretary for Preparedness and Response U.S. Department of Health and Human Services		
5:00 – 6:00 South Bldg Third Floor Ballroom A	Reception and Poster Session – Exhibit Hall		



Biomedical Advanced Research and Development Authority

INDUSTRY DAY

Wednesday, January 12, 2011

Walter E. Washington Convention Center

Middle Building, First Floor

PLENARY SESSION

9:00 – 10:30

Rooms 146 A and B

BARDA Strategy Update and New Initiatives for Medical Countermeasure Development, Acquisition, and Infrastructure Building

Robin A. Robinson, PhD

Deputy Assistant Secretary for Preparedness and Response
Director, Biomedical Advanced Research and Development Authority
U.S. Department of Health and Human Services

Break 10:30 – 11:00

PLATFORM TECHNOLOGIES

Room 146 A

Moderator: Phil Ferro, PhD, MS

Director
Office of Portfolio Management
Biomedical Advanced Research and Development Authority

THERAPEUTICS – Rad/Nuc

Room 146 B

Moderator: Ronald G. Manning, PhD

Chief
Chemical, Radiological & Nuclear Medical Countermeasures
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority

THERAPEUTICS

Room 146 C

Moderator: Gary L. Disbrow, PhD

Deputy Director
Division of Chemical, Biological, Radiological
and Nuclear Countermeasures
Biomedical Advanced Research and Development Authority

11:00 – 11:22

**Good Laboratory Practices (GLP) -
Compliant Preclinical Development of
Medical Countermeasures and Devices
Combined with State of the Art Imaging
at the Texas A&M Institute for
Preclinical Studies**

Terry Fossum
Texas A&M University

11:00 – 11:22

**Rx100 – A Potent Radiomitigator for
Acute Radiation Syndrome
(HEM-ARS and GI-ARS)**

Gabor Tigyi
RxBio, Inc.

11:00 – 11:22

**AVP-21D9, a Human Monoclonal
Antibody Against *B. anthracis*
Protective Antigen, for the Treatment
of Inhalation Anthrax**

Ronald T. Aimes
Emergent Biosolutions

11:23 – 11:45

**A Needle Free Injection Technology
for Subcutaneous, Intramuscular &
Intradermal Injections**

Richard Stout
Bioject, Inc.

11:23 – 11:45

**Pharmacological Quiescence™ (PQ™):
A Novel Approach for Radiomitigation
of the Hematologic Syndrome After
Radiation Exposure**

Norman E. Sharpless
G-Zero Therapeutics

11:23 – 11:45

**Recombinant Human CC10 Protein
Therapeutic for
Severe Respiratory Infection**

Aprile L. Pilon
Clarassance, Inc.

11:46 – 12:09

**Single-Use Upstream Processing
in Modular Manufacturing for
Rapid MCM Response**

Matt Kremer
Artelis

11:46 – 12:09

**PRM-151, a Novel Therapeutic Agent
to Treat Post-Radiation
Epithelial Injury and Fibrosis**

Mark Lupher
Promedior, Inc.

11:46 – 12:09

**Development of a High Temperature
Stable Lyophilized Formulation
for XOMA 3AB, a BoNT/A Triple
Antibody Product**

Joel Freeberg
XOMA US LLC

Lunch On Your Own 12:10 – 1:30
Convention Center Concessions located in Middle Building, Second Floor

PLATFORM TECHNOLOGIES Room 146 A Moderator: Brian R. Moyer, MS <small>Science Advisor Acute Radiation Syndrome and Chemical Injury Division of CBRN Countermeasures Biomedical Advanced Research and Development Authority</small>	VACCINES Room 146 B Moderator: Narayan Iyer, PhD <small>Project Officer Chemical, Radiological & Nuclear Medical Countermeasures Division of CBRN Countermeasures Biomedical Advanced Research and Development Authority</small>	THERAPEUTICS Room 146 C Moderator: John Esker <small>Project Officer Chemical, Radiological & Nuclear Medical Countermeasures Division of CBRN Countermeasures Biomedical Advanced Research and Development Authority</small>
<p style="text-align: right;">1:30 – 1:52</p> <p>Increasing the Availability and Surge Manufacturing Capacity of Key Antiviral Medications</p> <p style="text-align: center;">Oliver Dapremont AMPAC Fine Chemicals</p>	<p style="text-align: right;">1:30 – 1:52</p> <p>Universal Influenza Vaccine (N8295) In Phase 1 Clinical Development May Facilitate Rapid Pandemic Response</p> <p style="text-align: center;">Rob Janssen Dynavax Technologies</p>	<p style="text-align: right;">1:30 – 1:52</p> <p>DAS181 (Fludase®) a Broad-Spectrum Therapeutic and Prophylactic Agent for Pandemic Influenza in Phase II</p> <p style="text-align: center;">David Wurtman NexBio</p>
<p style="text-align: right;">1:53 – 2:15</p> <p>An Advanced Vaccine Targeting Platform for Biodefense Countermeasures</p> <p style="text-align: center;">Serguei Kisselev BioProtection Systems Corp.</p>	<p style="text-align: right;">1:53 – 2:15</p> <p>Safety, Immunogenicity and Productivity of Recombinant Influenza A Vaccine Constructs for HA1 California/07, Novel H1N1 in Healthy Adults 18-49 and >65 Years of Age</p> <p style="text-align: center;">David N. Taylor Vaxxinate Corp.</p>	<p style="text-align: right;">1:53 – 2:15</p> <p>Clinical Experience with Cangene-Manufactured Medical Countermeasures Released from the Strategic National Stockpile</p> <p style="text-align: center;">Chris Sinclair Cangene Corp.</p>
<p style="text-align: right;">2:16 – 2:38</p> <p>Medicago: Innovative Technologies for Next Generation Vaccines Based on Virus-like Particles</p> <p style="text-align: center;">Frederic Ors Medicago, Inc.</p>	<p style="text-align: right;">2:16 – 2:38</p> <p>GelVac™ Nasal Dry-Powder Vaccine Platform for Influenza and Biodefense Vaccines</p> <p style="text-align: center;">James Talton Nanotherapeutics, Inc.</p>	<p style="text-align: right;">2:16 – 2:38</p> <p>Solithromycin (CEM-101): Broad Spectrum Antibiotic Countermeasure</p> <p style="text-align: center;">Prabhavathi Fernandes Cempra Pharmaceuticals</p>
<p style="text-align: right;">2:39 – 3:01</p> <p>A Broad Spectrum Antiviral Platform Technology</p> <p style="text-align: center;">Jim Joyce Aethlon Medical</p>	<p style="text-align: right;">2:39 – 3:01</p> <p>Genomes-to-Vaccines Development of an Efficacious Epitope-Based Smallpox Vaccine</p> <p style="text-align: center;">Leonard Moise EpiVax</p>	<p style="text-align: right;">2:39 – 3:01</p> <p>AEOL 10150 - A Broad Spectrum Medical Countermeasure for Nuclear and Chemical Threats</p> <p style="text-align: center;">John L. McManus Aeolus Pharmaceuticals, Inc.</p>
<p style="text-align: right;">3:02 – 3:24</p> <p>Bavarian Nordic's MVA-BN® Vaccine Technology Platform</p> <p style="text-align: center;">Paul Chaplin Bavarian Nordic</p>	<p style="text-align: right;">3:02 – 3:24</p> <p>Nanoemulsion Adjuvanted Killed Nasal Influenza Vaccine: Results of a Phase I Clinical Trial</p> <p style="text-align: center;">Jakub K. Simon NanoBio Corp.</p>	<p style="text-align: right;">3:02 – 3:24</p> <p>PRX-105: A Novel Biological Countermeasure for Nerve Agents</p> <p style="text-align: center;">Carmit Nadri Protalix Biotherapeutics</p>

Break 3:30 – 3:50

NON-PHARMACEUTICAL MEDICAL COUNTERMEASURES <i>Room 146 A</i> Moderator: Lorraine M. Harkavy Project Officer Division of Influenza Biomedical Advanced Research and Development Authority	PLENARY SESSION <i>Room 146 B</i> Moderator: Famane Brown, MPA Chief of Acquisition Policy Office of Acquisition Management, Contracts and Grants Assistant Secretary of Preparedness and Response U.S. Department of Health and Human Services	THERAPEUTICS <i>Room 146 C</i> Moderator: Marcy Beth Grace, PhD Project Officer Chemical, Biological, Radiological & Nuclear Diagnostics Division of CBRN Countermeasures Biomedical Advanced Research and Development Authority
3:50 – 4:12 Protection from Inhaled Infectious Aerosols: Importance of Source Control Mohamed Mansour Stony Brook University	3:50 – 4:58 Innovative Contracting Famane Brown, MPA Chief of Acquisition Policy Glynis Fisher Section Chief Chemical Biological Radiological Nuclear Research and Development Michael Younkins, MBA Contracting Officer	3:50 – 4:12 EPR Dosimetry for Triage after a Major Radiation Event Harold Swartz Clin-EPR, LLC
4:13 – 4:35 Pasture USA Jr. Mask Milton Grin Borlan Sciences	4:13 – 4:58 Office of Acquisition Management, Contracts and Grants Office of the Assistant Secretary for Preparedness and Response U.S. Department of Health & Human Services	4:13 – 4:35 Cell Based Treatments for Burn and Trauma Wounds Richard Snell Altrika Ltd
4:36 – 4:58 Advanced Surgical Masks and Respirators - Anti viral Kathryn Whitlow C&A Biosciences International		4:36 – 4:58 Comparison of Functional Activity and Pharmacokinetic Data from Nonclinical Valortim® Efficacy Studies: Implications for the Animal Rule James Bourdage PharmAthene